

REMARKS

Claims 1 and 3-14 were pending in the present application. Claims 1, 3-9 and 11-14 were variously rejected under 35 U.S.C. §103.

By this amendment, claim 1 has been amended and new claim 15 has been added without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment and new claim can be found, *inter alia*, throughout the specification, for example, at page 2, lines 13-25, Examples at pages 7 and 8, and originally filed claim 1.

As discussed herein, the amendment is made to better place the application in condition for allowance by more clearly indicating a difference between the instant invention and the cited references acknowledged by the Examiner.¹ Thus, Applicants respectfully submit that the amendment is does not raise new issues and respectfully request entry of this amendment.

The amendments are made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under 35 U.S.C. §103

Claims 1, 3-9 and 11-13 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jaeger (U.S. Pat. No. 3,268,606) in view of Sarnecki (U.S. Pat. No. 3,356,753).

¹ See, Final Office Action, page 4.

Claims 1, 3-9 and 11-14 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Jaeger in view of Sarnecki, and further in view of Rose et al. (U.S. Pat. No. 5,378,369, "Rose") and Bohinski et al. (U.S. Pat. No. 3,492,202, "Bohinski"). Applicants respectfully traverse these rejections.

The present invention is directed to a process which involves the direct separation of the carotenoid crystals from the microbial biomass without solubilizing the carotenoid crystals.

Both Jaeger and Sarnecki describe processes in which carotenoids are solubilized and then crystallized, as discussed in the previously filed response to the Office Action.² The Examiner clearly acknowledges this difference in the outstanding rejection in stating that Applicants are "correct in asserting that the cited references disclose processes wherein the carotenoids are solubilized and then crystallized" but the Examiner also states that the claims "are still sufficiently broad to encompass the processes suggested by Jaeger, Sarnecki and the other cited references."

As amended herein, the claimed invention is directed to a process for the direct isolation of a crystalline carotenoid compound from a microbial biomass. As clearly described in the specification and now stated in the claim language, the direct isolation process of the invention is performed without a carotenoid solubilization step.

Thus, contrary to the instant claimed invention, the carotenoid isolation processes taught by Jaeger and Sarnecki rely on the solubilization and subsequent crystallization of carotenoid crystals. Accordingly, the cited references, alone or in combination, do not teach the claimed invention.

On page 6 of the Final Office Action, the Examiner asserts that claims 5-7 make "it particularly evident that applicant's claims encompass the solvent extraction steps of Jaeger" and cites column 2, lines 22-36 of Jaeger in support. Applicants respectfully disagree with this assertion and interpretation of the claimed invention.

² See Amendment and Response to non-final Office Action filed October 29, 2003, for example, at page 6.

Jaeger describes a procedure in which β -carotene in a dry mycelium preparation is solubilized with a solvent, the solvent is recovered and the solubilized β -carotene in the solvent is then crystallized. Again, the claimed invention is a process for the direct isolation of a crystalline carotenoid compound without a carotenoid solubilization step. Accordingly, when dependent claims 5-7 call for use of a "solvent immiscible with water," it is done so in the context of claim 1 and, thus, not for use in carotenoid solubilization.

Further, there is no suggestion or motivation in the references or in the art to modify Jaeger and Sarnecki to arrive at the claimed invention.

Accordingly, the combination of Jaeger and Sarnecki do not support a *prima facie* case of obviousness.

Rose also describes a process of solvent extraction of β -carotene from a biomass suspension. For example, Rose teaches a process "whereby the β -carotene is caused to dissolve in the organic phase, followed by separation of the organic phase from the aqueous phase." Rose, column 1, lines 17-20, and column 4, lines 47-49.

The Examiner asserts that Bohinski "provides motivation for adding vegetable oil to the microbial cells before cell disruption." Final Office Action, page 4. However, Bohinski describes a method for improving yields of β -carotene produced in a nutrient media containing soapstock and does not describe a process for isolation of β -carotene crystals. Bohinski describes the amount of β -carotene produced by cells when grown with oil or soapstock (see, for example, column 5, lines 5-8) but does not teach or suggest a method for isolating a crystalline carotenoid compound as claimed in the instant invention.

Neither Rose nor Bohinski supply what is missing from Jaeger in view of Sarnecki and the combinations of Jaeger, Sarnecki, Rose and Bohinski do not teach or suggest the claimed invention, thus do not render the claimed invention obvious. None of the references, either alone or

in combination, describes or suggests a process for direct isolation of crystalline carotenoid compound without a carotenoid solubilization step.

Further, Applicants submit that there is no suggestion in the art or in these references to modify their teachings to arrive at the claimed invention.

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established in view of the cited references.

Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, entry of the amendment and reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246152019901. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 19, 2004

Respectfully submitted,

By Karen Zachow
Karen Zachow

Registration No.: 46,332
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-5191